K111446

DEC 2 1 2011

4. 510(K) SUMMARY

This 510(k) summary is being submitted in accordance with the Medical Device Amendments of 1976, the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21CFR 807.92.

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Date of 510(k) Summary Preparation: November 28, 2011

Device that is the subject of this notification:

Trade/Proprietary Name: The Sovereign Compact Phacoemulsification System
Classification Name: Phacofragmentation System

Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation system
Regulatory Class: Class II
Product Code: HQC

The devices to which substantial equivalence is claimed:

Table 4-1: Predicate Devices to Which Substantial Equivalence is Claimed

Predicate Device Name	Predicate Trade Name	510(k) Holder	510(k) Number	Clearance Date
Sovereign Compact Phacoemulsification System Predicate Devices				
Mojave Cataract Extraction System	Sovereign Compact	AMO	K003638	02/13/2001
AMO Ophthalmic Surgical System	WhiteStar Signature	AMO	K060366	04/07/2006
AMO Ultrasonic Handpiece 690880 Predicate Device				
Sovereign Phaco Handpiece	Sovereign Handpiece	AMO	K981116	05/19/1998

4.1 DEVICE DESCRIPTION SUMMARY

The Sovereign Compact Phacoemulsification System (The System) is a modular ophthalmic microsurgical system that facilitates anterior segment (cataract) surgery for the disruption and extraction of a cataractous lens. As with other phacofragmentation systems, The System is identified in 21 CFR 886.4670 as a "phacofragmentation system that is an AC-powered device with a fragmenting needle intended for use in cataract surgery to disrupt a cataract with ultrasound and extract the cataract."

The main performance functions of The System include ultrasonic phacoemulsification, diathermy, irrigation and aspiration, and vitrectomy. Ultrasonic phacoemulsification provides vibration at an ultrasonic frequency when used in conjunction with a compatible AMO ultrasonic handpiece. The System is controlled and powered by The System console, which includes an active color graphic user interface and receptacles for an automated IV pole, footpedal, remote control, and drainage packs.

The materials, basic scientific concepts, physical properties and intended use of The System are identical to those of The Mojave Cataract Extraction System (branded as Sovereign Compact) (K003638) predicate device. The AMO Ophthalmic Surgical System was also listed as a predicate because it shares the same available software modes as The System. Both predicate devices are manufactured by Abbott Medical Optics Inc. (AMO).

The System will be marketed as either a complete unit or an optional software upgrade kit for current Sovereign Compact Systems in the field.

In addition, the enhancements made to The System include an optional feature-activated capability for the use of the AMO Ultrasonic Handpiece 690880 (Handpiece 690880), which is substantially equivalent to the Sovereign Phaco Handpiece cleared under the Sovereign Cataract Extraction System 510(k) (K981116). Handpiece 690880 is intended for use during the phacoemulsification procedure to break up (emulsify) the nucleus of the cataractous lens and remove the remaining nuclear fragments.

4.2 INDICATIONS FOR USE

The Sovereign Compact Phacoemulsification System is an AC-powered device with a fragmenting needle intended for use in cataract surgery to disrupt a cataract with ultrasound and extract the cataract.

4.3 TECHNOLOGICAL CHARACTERISTICS

For anterior segment (cataract) surgical procedures, the system provides the following main modes: diathermy, phacoemulsification, irrigation and aspiration, and vitrectomy. The technological characteristics of the device are substantially equivalent to those cleared under the 510(k)s of the Mojave Cataract Extraction System (K003638) and the AMO Ophthalmic Surgical System (K060366). The technological characteristics of the AMO Ultrasonic Handpiece are substantially equivalent to those of the Sovereign Phaco Handpiece cleared under 510(k) of the Sovereign Cataract Extraction System (K981116).

The System, which is the subject device, is an upgrade to the existing predicate device, the Mojave Cataract Extraction System (branded as Sovereign Compact and cleared on February 13, 2001 under K003638). Since the clearance of this device, The System has been upgraded

to include software modes that are also available with the second predicate, the AMO Ophthalmic Surgical System (K060366).
The differences between The System and its two predicate devices include:

- AMO Ultrasonic Handpiece 690880 compatibility
- Support for the latest version of the Surgical Media Center (SMC)
- The ability to view vacuum units in kilopascals (kPa)
- Support for an IV pole extension

A comparison summary of The System and the two predicate devices is provided in Table 4-2. All unique features available with The System with respect to both predicates are underlined for clarity.

Table 4-2 Comparison Overview of The System to the Predicate Devices

Features and Characteristics	Proposed Device The Sovereign Compact Phacoemulsification System	Predicate Device Mojave Cataract Extraction System (K003638)	Predicate Device AMO Ophthalmic Surgical System (K060366)
Intended Use	Anterior Segment Ophthalmic Surgery	Anterior Segment Ophthalmic Surgery	Anterior and Posterior (optional) Segment Ophthalmic Surgery
Technological Characteristics			
User Interface	Key panel, remote control, footpedal	Key panel, remote control, footpedal	Touch screen, remote control, footpedal
Hardware: -Console	Compact system console with display screen and key entry	Compact system console with display screen and key entry	Upper-Tier system console with display screen and key entry
-Footpedal	Wired (closed or open-toe)	Wired (closed toe)	Wired or wireless (open-toe)
-Remote control unit	Wired	Wired	Wireless
-Console stand	Cart with mayo tray and articulating arm	Cart with mayo tray and articulating arm	Cart with mayo tray and articulating arm
-IV Pole	Yes (with optional extension)	Yes	Yes
Software: -OS for Safety Critical Functions	Same	Same	Same
Available Modes:	Same	No	Same
Specifications: -Aspiration Pump Type	Peristaltic	Peristaltic	Peristaltic and Venturi
- Handpiece 690880 compatibility	Yes	No	No
-SMC Support	Yes	No	No
-Multilingual support	Yes	No	Yes
-Vacuum/pressure	mmHg, kPa	mmHg	mmHg

Features and Characteristics Accessories	Proposed Device The Sovereign Compact Phacoemulsification System	Predicate Device Mojave Cataract Extraction System (K003638)	Predicate Device AMO Ophthalmic Surgical System (K060366)
Disposable Accessories	• Tips and Sleeves • Fluidics Packs • Administration Set • Sterilization Tray • Phaco Handpieces	• Tips and Sleeves • Fluidics Packs • Administration Set • Sterilization Tray • Phaco Handpieces	• Tips and Sleeves • Fluidics Packs • Administration Set • Sterilization Tray • Phaco Handpieces
Reusable Accessories	• Fluidics Pack • Irrigation/Aspiration Handpiece • Diathermy Cord with Bipolar Forceps • Vitrectomy Handpiece	• Fluidics Pack • Irrigation/Aspiration Handpiece • Diathermy Cord with Bipolar Forceps • Vitrectomy Handpiece	• N/A (Disposable Only) • Irrigation/Aspiration Handpiece • Diathermy Cord with Bipolar Forceps • Vitrectomy Handpiece

4.4 SUMMARY OF NON-CLINICAL TESTS

The System and Handpiece 690880 have undergone testing and are in compliance with applicable safety standards. The subject device was found to perform equivalently to the predicate device during the following modes of anterior segement ophthalmic surgery: phacoemulsification, irrigation,/aspiration, diathermy and vitrectomy. Therefore, the subject device and the predicate devices have similar safety, effectiveness, and performance profiles.

4.5 SUMMARY OF CLINICAL TESTS

No clinical studies were deemed necessary to determine the safety and effectiveness or substantial equivalence of The System and Handpiece 690880 to their predicate devices.

4.5 CONCLUSIONS

The technological characteristics that determine the functionality and performance of The Sovereign Compact Phacoemulsification System and the AMO Ultrasonic Handpiece 690880 are substantially equivalent to those of the predicate devices listed. The Sovereign Compact Phacoemulsification System and the AMO Ultrasonic Handpiece will be manufactured in compliance with FDA and ISO quality systems requirements. The data presented from the nonclinical tests demonstrate that the device is safe and effective, and performs as safely and effectively as the legally marketed predicate devices. Validation and verification demonstrates that the functional requirements and specifications have been met prior to commercial release.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 2 1 2011

Abbott Medical Optics, Inc.
c/o Rosanne Yetemian, PhD, MSRS
Regulatory Affairs Specialist
1700 E. St. Andrew Place
Santa Ana, CA 92705

Re: K111446
Trade/Device Name: Sovereign Compact Phacoemulsification System
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation system
Regulatory Class: Class II
Product Code: HQC
Dated: December 19, 2011
Received: December 20, 2011

Dear Dr. Yetemian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111446

Device Name: The Sovereign Compact Phacoemulsification System

Indications For Use:

The Sovereign Compact Phacoemulsification System is an AC-powered device with a fragmenting needle intended for use in cataract surgery to disrupt a cataract with ultrasound and extract the cataract.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K111446